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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,113

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Jon Lundberg

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EXAMINER

LANDRY II, GERALD ERNEST

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

09/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,113	Applicant(s) LUNDBERG ET AL.	
	Examiner GERALD LANDRY II	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-100 is/are pending in the application.
- 4a) Of the above claim(s) 1-53,68-94 and 98-100 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-67 and 95-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/28/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: page 6 of the specification identifies element number 17 as both a collection bag and a volume of urine.

Appropriate correction is required.

2. The Examiner would like to remind the applicant of proper "means or step plus function" limitations in a claim:

A claim limitation will be presumed to invoke 35 U.S.C. **112**, sixth paragraph, if it meets the following 3-prong analysis:

(A) the claim limitations must use the phrase "means for" or "step for;"

(B) the "means for" or "step for" must be modified by functional language; and

(C) the phrase "means for" or "step for" must not be modified by sufficient structure, material, or acts for achieving the specified function.

With respect to the first prong of this analysis, a claim element that does not include the phrase "means for" or "step for" will not be considered to invoke 35 U.S.C. **112**, sixth paragraph. If an applicant wishes to have the claim limitation treated under 35 U.S.C. **112**, sixth paragraph, applicant must either: (A) amend the claim to include the phrase "means for" or "step for" in accordance with these guidelines; or (B) show that even though the phrase "means for" or "step for" is not used, the claim limitation is written as a function to be performed and does not recite sufficient structure, material, or acts which would preclude application of 35 U.S.C. **112**, sixth paragraph. See *Watts v. XL Systems, Inc.*, 232 F.3d 877, 56 USPQ2d 1836 (Fed. Cir. 2000) (Claim limitations were held not to invoke **35 U.S.C. 112**, sixth paragraph, because the absence of the term "means" raised the presumption that the limitations were not in means-plus-function form and the applicant did not rebut that presumption.); see also *Masco Corp. v. United States*, 303 F.3d 1316, 1327, 64 USPQ2d 1182, 1189 (Fed. Cir. 2002) ("[W]here a method claim does not contain the term 'step[s] for,' a limitation of that claim cannot be construed as a step-plus-function limitation without a showing that the limitation contains no act.").

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 54-67 and 95-97 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,824,049 to Ragheb et al.

Regarding claims 54-67, and 95-97, Ragheb teaches a device **(10)** for insertion in a human or animal body or body cavity, the device having an inflatable and expandable means **(12, 18)** containing a solution of about pH 1-5.5 which comprises at least one component capable of releasing at least one low molecular antimicrobial compound (LMAC) **(column 8 line 3 – column 10 line 15)** capable of permeating into the adjacent tissue or body cavity and the at least one component releases the LMAC upon acidification; wherein the LMAC is released when the at least one component is contacted with a second component **(device in contact with tissue (column 9 lines 10-11), bioactive material layer in contact with porous outer layer (column 10 lines 30-34), column 18 lines 5-25)**; wherein the at least one component is inorganic nitrite **(column 9 line 24 - column 10 line 15: “nitric oxide promoter”)**; wherein the second component is ascorbic acid or acetic acid **(column 9 line 24 – column 10 line 15: “ascorbic acid”)**; wherein the at least one component is inorganic nitrite and the second component is ascorbic acid or acetic acid **(column 9 line 24—column 10 line 15)**; wherein the contact is accomplished through the introduction of a liquid to the means and the liquid being selected from the group consisting of water, saline, or any physiological buffer **(porous layer 20 acts as a buffer; columns 8 - 10)**; wherein the device is a catheter for insertion into the urinary tract **(column 3 lines 10-41)** of the human or animal body and the inflatable and expandable means comprise an inflatable cuff **(12, 18, figure 9)**; wherein the cuff when inserted into the urinary

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tract is situated in the urinary bladder (**inherent and implied in columns 3-5 and abstract**); wherein the device is an intratracheal tube (**abstract: “trachea”**); wherein the device is a gastric tube (**abstract: “esophagus, colon, biliary tract”**); wherein the LMAC is a reactive nitrogen intermediate, a reactive oxygen intermediate or a combination of these two (**column 9 line 24 – column 10 line 15**); wherein the LMAC is selected from the group consisting of nitric oxide (NO), NO₂, N₂O₃, N₂O₄, HNO₃, HNO₂, NO⁺, NO⁻, O²⁻, O₃, singlet oxygen, H₂O₂, OONO⁻, HOONO, NOCl, NOSC₃N, NO thiocyanate, an OH radical and HOCl (**column 9 line 24 – column 10 line 15**); wherein the LMAC is in a gaseous state at body temperature (**implied in column 9 line 24 – column 10 line 15**); having a concentration of one or more metal ions in the contents of the inflatable and expandable means or in the material or on the surface of the device, the concentration being sufficient to increase the antimicrobial effect (**column 5 lines 1-9, column 7 lines 34-37**); wherein the device is a vascular catheter (**abstract**); wherein the device is a vascular catheter port (**implied in abstract**); wherein the device is a wound drain tube (**capability displayed in abstract**).

5. Claims 54, 60, and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,049,140 to Brenner et al.

Regarding claims 54, 60, and 61, Brenner teaches a device (**10**) for insertion in a human or animal body or body cavity, the device having an inflatable and expandable means (**12, plus inflatable/expandable means shown in figure 1**) containing a solution of about pH 1-5.5 which comprises at least one component capable of releasing at least one low molecular antimicrobial compound (LMAC) capable of permeating into the adjacent tissue or body cavity and the at least one component releases the LMAC upon acidification (**column 2 lines 35-48**); wherein the

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device is a catheter for insertion into the urinary tract of the human or animal body (**column 1 lines 55-60**) and the inflatable and expandable means comprise an inflatable cuff (**column 2 lines 35-40**); wherein the cuff when inserted into the urinary tract is situated in the urinary bladder (**inherent**).

6. Claims 54, 55, 60, and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,505,695 to Eplett Jr.

Regarding claims 54, 55, 60, and 61, Eplett Jr. teaches a device for insertion in a human or animal body or body cavity, the device having an inflatable and expandable means containing a solution of about pH 1-5.5 which comprises at least one component capable of releasing at least one low molecular antimicrobial compound (LMAC) capable of permeating into the adjacent tissue or body cavity and the at least one component releases the LMAC upon acidification (**figure 1, abstract, columns 1-3**); wherein the LMAC is released when the at least one component is contacted with a second component (**multiple layers (10) disclosed in column 2 lines 54-63; contact between elements 3 and 4 as shown in figure 1**); wherein the device is a catheter for insertion into the urinary tract of the human or animal body (**figure 1**) and the inflatable and expandable means comprise an inflatable cuff (**4**); wherein the cuff when inserted into the urinary tract is situated in the urinary bladder (**implied in column 2 lines 30-40**).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GERALD LANDRY II whose telephone number is (571)270-7409. The examiner can normally be reached on M-F, 7:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GEL/

Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763